

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

STATE OF NEW YORK, et al.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN
SERVICES, et al.,

Defendants.

20 Civ. 5583 (AKH)

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS'
MOTION TO DISMISS**

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INTRODUCTION

Defendants’ Rule 12(b)(1) motion to dismiss is a baseless attempt to skirt adjudication of the merits of a regulation that rescinded critical nondiscrimination protections for transgender people, women and others seeking reproductive health care, and individuals with limited English proficiency, and which significantly narrowed the scope of regulatory requirements designed to prevent discrimination in health care. *See* Final Rule, *Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority*, 85 Fed. Reg. 37,160 (June 19, 2020) (the “2020 Rule” or “Rule”). As explained in Plaintiffs’ Complaint and motion for summary judgment (ECF Nos. 1, 108-111), the Rule violates the APA because it is contrary to law, exceeds Defendants’ statutory authority, and is arbitrary and capricious.

Defendants’ motion to dismiss challenges Plaintiffs’ standing and argues that Plaintiffs’ claims as to certain aspects of the Rule are not ripe. But as explained below, Plaintiffs have standing because the Complaint plausibly alleges injuries to the States’ proprietary and quasi-sovereign interests that are traceable to Defendants’ promulgation of the Rule and would be redressed by its invalidation. Unless the 2020 Rule is vacated, the Rule has caused and will continue to cause Plaintiffs to suffer: (1) new administrative and regulatory costs; (2) additional investigation and enforcement costs; and (3) the burden of higher health care costs arising from adverse health impacts to their resident populations. These injuries accrue due to the effects of the Rule in its entirety, as well as the specific impact of each provision of the Rule challenged here. In addition, because the 2020 Rule is a final agency action reviewable under the APA, Defendants’ ripeness claims have no merit. The Court should deny Defendants’ motion.

BACKGROUND

Section 1557 was enacted in 2010 as part of the Affordable Care Act’s (“ACA”) comprehensive set of health care reforms to expand access to quality, affordable care in the

United States. In 2016, the U.S. Department of Health and Human Services (“HHS”) promulgated its first Section 1557 implementing regulations. Final Rule, *Nondiscrimination in Health and Health Education Programs and Activities*, 81 Fed. Reg. 31,376 (May 18, 2016) (“2016 Rule”).

Just over three years after the 2016 Rule took effect, HHS published a proposed rule to make substantial amendments to the 2016 regulations and other HHS regulations. Notice of Proposed Rulemaking, *Nondiscrimination in Health and Health Education Programs or Activities*, 84 Fed. Reg. 27,846 (June 14, 2019) (“2019 NPRM”). Following a notice-and-comment period, during which HHS received nearly 200,000 comments (mostly opposing the proposed rule), HHS finalized the 2020 Rule with minimal changes from the proposal. 85 Fed. Reg. at 37,161, 37,164-222. The 2020 Rule was published on June 19, 2020 and, except for certain provisions that were preliminarily enjoined in other lawsuits, took effect on August 18, 2020. *Id.* at 37,160.

Among other things, the 2020 Rule: (1) narrows the scope of covered health programs and activities to exclude certain health insurers and many of HHS’s own health programs and activities, *id.* at 37,162, 37,244-45 (§ 92.3); (2) eliminates the 2016 Rule’s definition of “on the basis of sex” (former § 92.4), which enumerated discrimination on the basis of gender identity, sex stereotyping, and pregnancy-related conditions as forms of prohibited sex discrimination, *id.* at 37,161-62; (3) eliminates express protections against sex discrimination for transgender people, including the requirement that transgender people be treated consistent with their gender identity (former § 92.206) and the provisions prohibiting covered health insurers from denying or limiting coverage for health services needed by transgender people in a discriminatory manner (former § 92.207(b)(3)-(5)), *id.*; (4) reduces covered entities’ obligation to provide meaningful

access to individuals with limited English proficiency (“LEP”) and related notice provisions (former § 92.201), *id.* at 37,162, 37,245-46 (§ 92.201); (5) adds broad religious exemptions and abortion exclusions permitting covered programs and activities from denying care in a manner otherwise prohibited by Section 1557, *id.* at 37,245 (§ 92.6(b)); and (6) deletes prohibitions on LGBTQ discrimination from other HHS regulations to “conform” to Section 1557, *id.* at 37,243 (amending 42 C.F.R. §§ 438.3, 438.206, 440.262, 460.98, 460.112); *see also id.* at 37,161-62, 37,218-22.¹

Plaintiffs—22 states and the District of Columbia (“Plaintiffs” or the “States”)—brought this action seeking vacatur of the 2020 Rule in its entirety. *See generally* Compl. (ECF No. 1).

LEGAL STANDARD

In opposing Defendants’ Rule 12(b)(1) motion to dismiss, Plaintiffs bear the burden of demonstrating that the Court has subject-matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Where, as here, “the Rule 12(b)(1) motion is facial, ‘that is, ‘based solely on the allegations of the complaint . . . the plaintiff has no evidentiary burden.’” *New York v. Scalia*, 464 F. Supp. 3d 528, 539 (S.D.N.Y. 2020) (“*Scalia I*”) (quoting *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 56 (2d Cir. 2016)). The Court must accept as true all material factual allegations in the complaint, and draw all reasonable inferences in Plaintiffs’ favor. *Id.* at 541.

To show standing, a “plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citing *Lujan*, 504 U.S. at 560-61). States “are not normal litigants for the purposes of invoking federal

¹ For additional background, Plaintiffs refer the Court to the discussion of Section 1557 and HHS’s related rulemaking in earlier briefing. *See* Pls.’ Mem. Supp. Mot. for Summ. J. 4-12 (ECF No. 109).

jurisdiction” and are “entitled to special solicitude in . . . standing analysis.” *Massachusetts v. EPA*, 549 U.S. 497, 518, 520 (2007); *see also New York v. U.S. Dep’t of Agric.*, 454 F. Supp. 3d 297, 303 (S.D.N.Y. 2020). In multi-plaintiff lawsuits, only one plaintiff need “have standing to sue” to satisfy Article III. *Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019).

To satisfy the injury-in-fact requirement at the pleading stage, a plaintiff must plausibly allege either actual or imminent harm or a concrete risk of harm. *Spokeo*, 136 S. Ct. at 1548; *see also NRDC v. FDA*, 710 F.3d 71, 82 (2d Cir. 2013) (requiring a “credible threat” of harm). “The injury-in-fact necessary for standing need not be large[;] an identifiable trifle will suffice.” *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002) (citation and quotation marks omitted). Allegations of a “future injury” qualify “if the threatened injury is ‘certainly impending,’ or there is a ‘substantial risk’ that the harm will occur.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409, 414 n.5 (2013)). The injury requirement is “a low threshold” meant only to ensure that “the plaintiff has a personal stake in the outcome of the controversy.” *John v. Whole Foods Mkt. Grp.*, 858 F.3d 732, 736 (2d Cir. 2017) (quotation marks omitted). “[A]n injury in fact ‘need not be capable of sustaining a valid cause of action,’ but instead ‘may simply be the fear or anxiety of future harm.’” *Amadei v. Nielsen*, 348 F. Supp. 3d 145, 157-58 (E.D.N.Y. 2018) (quoting *Ross v. Bank of Am., N.A. (USA)*, 524 F.3d 217, 222 (2d Cir. 2008)).

To satisfy the traceability requirement, a plaintiff must allege injuries that are “fairly traceable to the actions of the defendant.” *Bennett v. Spear*, 520 U.S. 154, 162 (1997). The plaintiff “need not prove a cause-and-effect relationship with absolute certainty; substantial likelihood of the alleged causality meets the test. This is true even in cases where the injury hinges on the reactions of third parties[.]” *NRDC v. Nat’l Highway Traffic Safety Admin.*, 894

F.3d 95, 104 (2d Cir. 2018) (citation and quotations omitted).

For redressability, a plaintiff “need not show that a favorable decision will relieve his *every* injury,” but only that the decision would redress “a discrete injury.” *Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982). A claim is redressable if the plaintiff “personally would benefit in a tangible way from the court’s intervention.” *Warth v. Seldin*, 422 U.S. 490, 508 (1975).

ARGUMENT

Plaintiffs’ complaint alleges injuries to their proprietary and quasi-sovereign interests that establish standing to challenge the 2020 Rule in its entirety and each of the central provisions at issue in this case. In addition, because the 2020 Rule is a final agency action reviewable under the APA, Defendants’ ripeness claims have no merit. The motion to dismiss should be denied.

I. Plaintiffs have standing to challenge the 2020 Rule in its entirety.

The States plausibly allege three injuries traceable to the 2020 Rule and redressable by its invalidation: (1) the States will incur administrative and regulatory costs to mitigate and counteract the public’s confusion and fear predictably resulting from the 2020 Rule; (2) the States will be forced to incur increased costs from the investigation and enforcement of state anti-discrimination laws for discrimination no longer covered by the Rule; and (3) the States and their residents will suffer public health harms and incur uncompensated care costs because the Rule reestablishes discriminatory barriers to health care access, which will result in delayed or denied health care.

A. The States will incur significant administrative costs to address the 2020 Rule’s significant changes to HHS’s Section 1557 regulations.

The States have sufficiently asserted concrete, particularized, and actual or imminent administrative burdens and expenses traceable to the Final Rule and redressable by its invalidation, including (1) issuing new or revised guidance, regulations, or legislation clarifying

distinct state standards and specifying that more stringent state law standards governing anti-discrimination in health care continue to apply even with the changes to federal policy;

(2) engaging in public education initiatives to address and counteract the public's fear and confusion resulting from the Rule's drastic changes to HHS's Section 1557 regulations; and

(3) training employees, regulated entities, and the public on their nondiscrimination obligations under state and federal law. Compl. ¶¶ 175-206.

“Monetary expenditures to mitigate and recover from harms that could have been prevented absent [an agency action] are precisely the kind of pocketbook injury’ that constitute an injury to a proprietary interest for standing purposes.” *New York v. U.S. Dep’t of Labor*, 363 F. Supp. 3d 109, 126 (D.D.C. 2019) (quoting *Air All. Houston v. EPA*, 906 F.3d 1049, 1059-60 (D.C. Cir. 2018)); *see also New York v. U.S. Dep’t of Homeland Sec.*, 408 F. Supp. 3d 334, 343-44 (S.D.N.Y. 2019). Plaintiffs may base their standing on “reasonably incur[red] costs to mitigate or avoid” a substantial risk of harm. *Clapper*, 568 U.S. at 414 n.5. The States, which operate health programs and activities subject to Section 1557 (*e.g.*, state Medicaid programs, health insurance marketplaces) and which regulate other covered entities, have and will continue to incur administrative and other costs because of the significant changes to HHS's Section 1557 regulations made by the 2020 Rule, including changes at odds with the text of Section 1557.

Such costs are not, as Defendants contend, “voluntary” or “self-inflicted.” Defs.’ Mem. Supp. Mot. to Dismiss 21-22 (ECF No. 113) (“Defs.’ Mem.”). Rather, as courts have repeatedly held, “the alleged burden associated with educating the public about a new administrative rule is enough to confer standing. That is because these increased administrative costs are ‘predictable, likely, and imminent.’” *Scalia I*, 464 F. Supp. 3d at 545 (quoting *City & Cty. of San Francisco v. U.S. Citizenship & Immigration Servs.*, 408 F. Supp. 3d 1057, 1124 (N.D. Cal. 2019)); *see also*

Dep't of Labor, 363 F. Supp. 3d at 126 (holding that plaintiffs had standing “based on the Final Rule’s direct imposition of an increased regulatory burden on them,” which included expending regulatory resources to answer inquiries relating to the challenged rule and anticipated expenses for consumer education initiatives).

The Complaint alleges numerous examples of the administrative costs the States have incurred or will incur in response to the 2020 Rule’s sweeping rewrite of HHS’s Section 1557 regulations.² Compl. ¶¶ 182-206. Because the 2020 Rule drastically diminishes patients’ rights and reduces covered entities’ obligations across the board, the States must incur significant costs to address and counteract new conflicts between federal and state nondiscrimination protections, including educating the public, providers, and insurers of their continuing obligations under state law; implementing new state-level protections to ensure continuity of protections for covered groups; updating trainings, regulations, and guidance documents; and related actions. *Id.*

In large part, these costs must be incurred in response to the totality of the changes adopted by the 2020 Rule, *see id.* ¶¶ 177, 186, 192-94, 199, 200-01, 203, 205-06.³ For example, California’s Department of Insurance needed to clarify to regulated insurers that the 2020 Rule

² Although the Court need not review evidence of Plaintiffs’ alleged injuries to resolve the motion to dismiss, *see Scalia I*, 464 F. Supp. 3d at 539-40, Plaintiffs filed numerous declarations and other exhibits in connection with their motion for summary judgment that establish their injuries beyond genuine dispute. *See* Pls.’ Mem. Supp. Summ. J. 13-27 (ECF No. 109) (citing generally Exs. 1–53).

³ This includes provisions discussed in the Complaint that Plaintiffs have not specifically challenged in their summary judgment motion, including the 2020 Rule’s rescission of the 2016 Rule’s uniform enforcement standard and prohibition on associational discrimination. *See* Compl. ¶¶ 122-24, 272-79. Although the Complaint does not allege *specific* injuries arising from those discrete provisions, Plaintiffs’ need to expend resources to educate the public, regulated entities, and their own employees will necessarily encompass these changes. Because the relief sought by Plaintiffs’ motion for summary judgment—a vacatur of the 2020 Rule in its entirety—will functionally restore the 2016 regulations, any specific injuries attributable to these rescinded provisions will be redressed.

does not preempt stronger state anti-discrimination laws, and expects to increase staffing and expend resources to address ongoing confusion among regulated entities and the public arising from the Rule. *Id.* ¶ 186. State agencies in the District of Columbia, Illinois, Minnesota, New Jersey, New York, Rhode Island, Wisconsin, and other Plaintiff States credibly allege that they have been forced to undertake similar efforts as well. *Id.* ¶¶ 184, 192, 194, 200-01, 203, 205-06.

That some administrative costs have already been incurred does not, as Defendants suggest, defeat standing, Defs.’ Mem. 23, since Plaintiffs have alleged imminent, future harm and the need to continue incurring such administrative costs in response to the Rule. It is true that “invalidation of the Final Rule would not restore monies already expended, but it would halt the need for future state expenditures.” *Dep’t of Labor*, 363 F. Supp. 3d at 126; *see also New York v. Scalia*, No. 20-cv-1689, 2020 WL 5370871, at *11 (S.D.N.Y. Sept. 8, 2020) (“*Scalia II*”) (“[T]he increase in [the States’] administrative costs caused by the Final Rule is predictable, likely, and imminent and is probably occurring already.”) (internal quotation marks omitted). Plaintiffs’ Complaint includes numerous allegations of state expenditures yet to be incurred and that would be avoided if the Rule were vacated. For example, the District of Columbia Health Benefit Exchange “will need to provide updated guidance to assist grantees, who provide application and enrollment assistance to District residents seeking coverage through DC Health Link, the online health insurance marketplace operated by DC Health Benefit Exchange Authority.” *Id.* ¶ 192. And Minnesota’s Department of Human Rights “will need to conduct outreach and issue publications to ensure that the public understands they remain protected by state law.” *Id.* ¶ 200.

The Rule itself *concedes* that covered entities will face “additional costs” “regarding training and revision of policies and procedures.” 85 Fed. Reg. 37,163; *see also id.* at 37,236-38.

This acknowledgement alone establishes Plaintiffs’ standing and suffices to defeat Defendants’ motion to dismiss. *See, e.g., District of Columbia v. U.S. Dep’t of Agric.*, 444 F. Supp. 3d 1, 37 (D.D.C. 2020) (finding standing where agency “has actually ‘done much of the legwork’” in establishing harm) (quoting *Massachusetts v. U.S. Dep’t of Health & Human Servs.*, 923 F.3d 209, 224-25 (1st Cir. 2019)); *see also California v. Azar*, 911 F.3d 558, 572 (9th Cir. 2018); *Dep’t of Labor*, 363 F. Supp. 3d at 127.

B. The States will face increased enforcement costs to address complaints of discrimination that can no longer be pursued with HHS.

The States have also plausibly alleged direct and concrete injuries to state agencies in the form of increased enforcement costs. Compl. ¶¶ 207-21. “Expend[ing] more resources on the enforcement of state-law analogues” of the ACA also presents the kind of “pocketbook injury” that injures a state’s proprietary interests. *Scalia I*, 464 F. Supp. 3d at 544; *see also Dep’t of Labor*, 363 F. Supp. 3d at 125-27 (holding that states had standing because they expected to use state resources to investigate complaints and bring enforcement actions).

The States have sufficiently alleged that the 2020 Rule invites discrimination in health care and curtails federal enforcement of it, requiring States to fill the enforcement gap. Compl. ¶¶ 209-14. “[T]o maintain the same level of protection for their [residents], the States must increase the resources they devote to state-level analogues” of the ACA. *Scalia II*, 2020 WL 5370871, at *11. Moreover, contrary to Defendants’ suggestion that the States can simply ignore civil rights violations, Defs.’ Mem. 24-25, the Complaint plausibly alleges that many of the Plaintiffs are required to investigate meritorious complaints of health care discrimination and lack discretion to “decide” not to incur increased investigation and enforcement costs. *See, e.g.,* Compl. ¶ 215 (“[The California Department of Fair Employment and Housing] does not have discretion to decline to process complaints within its jurisdiction, so any increase in complaints

necessarily increases its workload.”);⁴ *id.* at ¶ 220 (“Michigan law requires that the Michigan Department of Civil Rights (‘MDCR’) investigate all complaints of discrimination . . .”).

Relatedly, Defendants suggest that the Rule’s weakened protections might benefit the States in their capacity as operators of covered health programs, by reducing “liability or penalties in the form of withheld federal financial assistance” if they discriminate, potentially outweighing the State’s costs traceable to the Rule. Defs.’ Mem. 15. This puzzling suggestion—that the States may benefit from an increase in health care discrimination—ignores both the facts and the law. On the facts, Plaintiffs’ Complaint plausibly alleges that health care discrimination leads to adverse health outcomes and additional expenses within Plaintiffs’ public health systems. *See infra* Part I.C. And on the law, even if hypothetical cost savings associated with unchecked discrimination against their residents were a legitimate “benefit”—which Plaintiffs reject—“the fact that an injury may be outweighed by other benefits . . . does not negate standing.” *Denney v. Deutsche Bank AG*, 443 F.3d 253, 265 (2d Cir. 2006).

Defendants argue that the States’ expected increase in enforcement costs is not fairly traceable to the Rule because the States can simply decide not to incur such costs. Defs.’ Mem. 24-25. As explained above, the Complaint plausibly alleges that the States cannot decline to investigate civil rights violations. And if Plaintiffs decline to issue new guidance or regulations to clarify applicable requirements in light of HHS’s rule change, confusion among consumers

⁴ Although Plaintiffs need only plausibly allege these injuries to survive Defendants’ motion to dismiss, the evidence shows that Plaintiffs are in fact already incurring these increased costs. At least one of the Plaintiffs’ agencies has received a complaint alleging discrimination based on transgender status. California’s Department of Fair Employment and Housing (“DFEH”) received a complaint alleging that health care providers denied medically necessary procedures to the complainant due to the complainant’s transgender status, despite the fact that the 2020 Rule has been preliminarily enjoined in part. *See* Kish Suppl. Decl. ¶ 5 (Ex. 54). Under the 2016 Rule, this complaint would have been handled by HHS rather than by DFEH; yet because of the 2020 Rule, DFEH must expend resources to address this complaint. *Id.*

and health care providers regarding the divergence between federal and state obligations will persist, leading to increased enforcement and public health care costs. The States’ “theory of standing thus does not rest on mere speculation about the decisions of third parties; it relies instead on the predictable effect of Government action on the decisions of third parties.” *Dep’t of Commerce*, 139 S. Ct. at 2566. The States have therefore satisfied the “relatively modest” burden of alleging traceability at the pleading stage. *Rothstein v. UBS AG*, 708 F.3d 82, 92-93 (2d Cir. 2013) (quoting *Bennett*, 520 U.S. at 171).

Defendants assert that the States cannot plausibly argue that the Rule will invite discrimination because “their own state laws and regulations explicitly prohibit the very discrimination that they claim the Rule will ‘invite[.]’” Defs.’ Mem. 24. To the contrary, Plaintiffs have plausibly alleged that discrimination against their residents will increase, as the Rule itself contemplates. Compl. ¶¶ 74, 83, 98, 177, 212-13, 226, 234, 254-55. First, as alleged in the Complaint, the Rule predicts that covered entities are likely to reduce protections in response to the Rule, Compl. ¶¶ 135, 136, 181. Second, even though most of the Plaintiff States have prohibitions against health care discrimination, such protections are not necessarily identical to the Section 1557 protections eliminated by the Rule. *See* Compl. ¶¶ 175, 248. Similarly, as Defendants recognize, the States cannot impose the same remedies as HHS, which can suspend or terminate federal financial assistance for violations of its regulations. *See* Defs.’ Mem. 15 (citing 85 Fed. Reg. at 54,192). Because “common sense and basic economics . . . tells us that the increased cost of unlawful conduct will make that conduct less common,” *NRDC*, 894 F.3d at 104-05 (internal citation omitted), the converse is also true: Reducing the costs of unlawful conduct will make such conduct more common.

In any event, Plaintiffs do not ultimately need to prove that discrimination has increased

as a result of the 2020 Rule; even if overall levels of discrimination remained constant, state enforcement agencies will predictably see an increase in discrimination *complaints* because HHS will no longer accept complaints against entities no longer covered by the 2020 Rule (*e.g.*, certain health insurers) or for conduct that is no longer prohibited by the Rule (*e.g.*, maintaining categorical coverage exclusions for services related to gender transition). Compl. ¶¶ 102, 209-11, 213-14. Plaintiffs’ allegations are sufficient to establish standing at the pleading stage.

Defendants also argue that the States have not adequately alleged redressability because, they imply, HHS has discretion to ignore complaints of violations of civil rights laws within the agency’s jurisdiction. Defs.’ Mem. 25. Although Defendants claim that “HHS is not under an ‘obligation’ to enforce all of its rules at all times against any arguable violator,” *id.*, the 2020 Rule expressly incorporates HHS’s enforcement procedures under its regulations implementing other civil rights laws, *see* 45 C.F.R. § 92.5, which all provide that HHS will process and investigate complaints alleging violations of those regulations’ protections, *see* 45 C.F.R. § 80.7 (Title VI regulation specifying that “the responsible Department official or his designee *will make a prompt investigation* whenever a . . . complaint, or any other information indicates a possible failure to comply with this part”) (emphasis added); 45 C.F.R. § 86.71 (Title IX regulation incorporating same); 45 C.F.R. § 84.61 (Section 504 regulation incorporating same); 45 C.F.R. §§ 90.43(c)(4)-(5) (describing complaint resolution procedures under the Age Discrimination Act requiring that an agency “*shall investigate complaints unresolved*” after mandatory mediation procedures and those unresolved during “early stages of the investigation”) (emphasis added). Furthermore, HHS’s own website explains that the Department’s Office for Civil Rights “will” initiate an investigation after it “determines if it has the legal authority to

review and investigate the complaint.”⁵ Under the 2020 Rule itself, HHS lacks discretion to turn away complaints, and Defendants’ contention to the contrary is plainly erroneous.

Defendants’ assertion that OCR’s investigations have resulted in “very few civil rights resolution agreements,” Defs.’ Mem. 25 n.4, is beside the point even if accurate. Of course, not all complaints result in findings of violations, and not all violations are resolved through resolution agreements. For standing purposes, it suffices that the States plausibly allege that they will likely receive, and need to process and investigate, discrimination complaints that previously could have been referred to and handled by HHS but—under the 2020 Rule—cannot be.

The cases on which Defendants rely—*Heckler v. Chaney*, 470 U.S. 821 (1985), and *Diamond v. Charles*, 476 U.S. 54 (1986)—do not command a different result. *Heckler*, which involved a challenge by death row inmates to the Food and Drug Administration’s decision not to take enforcement action with respect to drugs used for lethal injection in executions, stands only for the proposition that an agency’s individual decision not to enforce a law in its jurisdiction is presumptively unreviewable and that an agency’s decision not to commence enforcement proceedings in a particular instance is generally discretionary. 470 U.S. at 834-35. But where “there is ‘law to apply’ that provides ‘judicially manageable standards’ for judging an agency’s exercise of discretion,” such as an agency’s regulations, informal guidance, or internal procedures; and “where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures.” *Salazar v. King*, 822 F.3d 61, 76 (2d Cir. 2016) (quoting *Montilla*

⁵ U.S. Dep’t of Health & Human Servs., Office for Civil Rights, *What to Expect*, <https://www.hhs.gov/civil-rights/filing-a-complaint/what-to-expect/index.html> (last visited January 8, 2021). This is consistent with the procedures set forth in OCR’s Case Resolution Manual. See U.S. Dep’t of Health & Human Servs., Office for Civil Rights, Case Resolution Manual for Civil Rights Investigations, at 30 (June 16, 2009) (noting that after confirming the agency has jurisdiction, “OCR is required to undertake the prompt investigation of complaints of unlawful discrimination”) (Ex. 56).

v. I.N.S., 926 F.2d 162, 167 (2d Cir. 1991)). An agency’s failure to follow those procedures is reviewable.

In any event, Plaintiffs are not challenging an individual decision by HHS not to enforce a “particular provision” against “any arguable violator.” Defs.’ Mem. 25. Rather, Plaintiffs’ standing accrues from the harms resulting from the 2020 Rule, including that HHS will not accept or investigate Section 1557 complaints for previously prohibited conduct. *See* Compl. ¶¶ 209-11. The “increased burden of ‘hiring staff and designating staff time to regulation and enforcement of state and federal rules because of the [2020] Rule’” is sufficient for standing. *Scalia I*, 464 F. Supp. 3d at 544 (quoting *Dep’t of Labor*, 363 F. Supp. 3d at 126).

Defendants’ citation to *Diamond* similarly misses the point. Relying on *Diamond*, Defendants argue that the States cannot establish standing based on enforcement costs because a “private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another.” Defs.’ Mem. 25 (quoting *Diamond*, 476 U.S. at 64). But in *Diamond*, the Court simply held that a pediatrician’s general interests in enforcing an abortion statute “as a doctor, a father, and a protector of the unborn” did not give him standing to defend it, as the doctor alleged no direct financial impact resulting from the statute. *Diamond*, 476 U.S. at 65-67. Here, in contrast, the States do not allege a generic interest in HHS’s enforcement decisions, but instead allege actual, concrete economic injuries resulting from the Rule. *See supra* Parts I.A, I.C.

C. The 2020 Rule causes harm to the public health and imposes uncompensated care costs on the States.

The States separately have standing because they have plausibly alleged a likely increase in uncompensated health care costs flowing from the Rule. Compl. ¶¶ 222-56. States have standing to challenge federal action that increases health care costs paid by the States. *Dep’t of Agric.*, 454 F. Supp. 3d at 305-09; *Dep’t of Homeland Sec.*, 408 F. Supp. 3d at 343-44. The

complaint plausibly alleges that the 2020 Rule reduces regulatory protections for LGBTQ individuals, women and others seeking reproductive health care or with pregnancy-related conditions, LEP individuals, and individuals from all protected groups suffering discrimination by insurers no longer considered covered entities by the 2020 Rule, which will create confusion and cause some individuals to delay or avoid seeking care; this will result in worse health outcomes—harms that will be compounded by the COVID-19 pandemic. Compl. ¶¶ 223-50. In turn, the Complaint adequately alleges that the poorer health outcomes caused by the 2020 Rule will increase the States’ health care expenses. Compl. ¶¶ 251-56. These allegations suffice to establish injury-in-fact. *See California v. U.S. Dep’t of Homeland Sec.*, No. 19-cv-4975, 2020 WL 4440668, at *5 (N.D. Cal. Aug. 3, 2020) (holding that state plaintiffs demonstrated standing in their challenge to DHS’s public charge rule, which would deter individuals from seeking timely health care, based on increased costs to states from individuals’ delayed treatment).

The States’ uncompensated care costs are traceable to the Rule, and a favorable decision would redress them. *See, e.g., Dep’t of Labor*, 363 F. Supp. 3d at 127. Increased or irremediable discrimination in health care is a “predictable effect” of the 2020 Rule, because reducing or eliminating penalties for certain conduct will predictably lead to an increase in that conduct. *See NRDC v. U.S. Dep’t of Interior*, 397 F. Supp. 3d 430, 440 (S.D.N.Y. 2019) (“Once [the agency] promulgated the [rule], it was a hardly-speculative exercise in naked capitalism to predict that facilities would take advantage of it.”) (quoting *NRDC v. EPA*, 755 F.3d 1010, 1017 (D.C. Cir. 2014)); *see also NRDC*, 894 F.3d at 104 (plaintiffs “need not prove a cause-and-effect relationship with absolute certainty; substantial likelihood of the alleged causality meets the test”).

Defendants incorrectly assert that the Second Circuit’s recent decision in *XY Planning*

Network, LLC v. SEC, 963 F.3d 244 (2d Cir. 2020), should “dispose” of Plaintiffs’ asserted injury arising from increased public health costs. Defs.’ Mem. 11-12. *XY Planning* addressed state plaintiffs’ alleged standing resulting from a loss of tax revenue attributable to a challenged rule. 963 F.3d at 252-53. Here, Plaintiffs do not seek standing based on an alleged loss of tax revenue, but instead based on their injuries resulting from public health costs and other financial injuries traceable to the 2020 Rule. *XY Planning* did not discuss, let alone foreclose, state standing on those grounds—or, for that matter, foreclose state standing based on lost tax revenues in other circumstances. *See Scalia II*, 2020 WL 5370871, at *13 (“[*XY Planning*] does not preclude the States from establishing standing based on decreased tax revenue.”) Rather, the decision simply reaffirmed the principle that “[a] state has Article III standing to challenge a federal regulation if it can show ‘a direct injury in the form of a loss of specific tax revenues,’” but held that the facts before it did not satisfy standing requirements because the causal chain between a regulation governing the duty of care owed by broker-dealers providing investment advice and the states’ collection of capital-gain taxes was “too attenuated and speculative.” *XY Planning*, 963 F.3d at 252-53 (quoting *Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992)). Because Plaintiffs do not seek standing based on a loss of tax revenue, and because their proprietary harms are traceable to the 2020 Rule, *XY Planning* has no bearing here.

D. The 2020 Rule harms Plaintiffs’ quasi-sovereign interests in the health and well-being of their residents.

To assert standing as *parens patriae*, a state must articulate “a quasi-sovereign interest in the health and well-being” of its residents. *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982). A state may invoke *parens patriae* interests in an action against the federal government to enforce federal law. *See Massachusetts*, 549 U.S. at 518, 520 n.17. Here, the States sue to enforce the ACA based on their *parens patriae* interests in “the

health and well-being of adults and children who live in their states.” Compl. ¶ 222. The States have plausibly alleged that the 2020 Rule will have adverse health consequences for the States’ residents, or at least create a concrete risk of those consequences. Compl. ¶¶ 223-50.⁶

Defendants, citing *Snapp*, 458 U.S. at 610 n.16, argue in a footnote that the States may not invoke *parens patriae* interests to sue the federal government. Defs.’ Mem. 10 n.2. But *Snapp* has never been applied in this Circuit to bar *parens patriae* suits; Defendants otherwise cite non-controlling, out-of-circuit opinions. In the Second Circuit, states have regularly been found to have *parens patriae* standing to sue federal agencies. *See, e.g., Carey v. Klutznick*, 637 F.2d 834, 838 (2d Cir. 1980) (holding that state “has standing in its capacity as *parens patriae*” to sue Census Bureau).⁷ Recently, a court in this District held that “states possess standing to ‘prevent[] an administrative agency from violating a federal statute’ in order to ‘vindicate the Congressional will.’” *Vullo v. OCC*, 378 F. Supp. 3d 271, 284 (S.D.N.Y. 2019) (quoting *Abrams v. Heckler*, 582 F. Supp. 1155, 1159 (S.D.N.Y. 1984)). Here, the States seek to vindicate the congressional will because HHS has violated the ACA and the APA. *See id.* at 287 (recognizing “the *parens patriae* framework of standing . . . permitting states to vindicate the congressional

⁶ Plaintiffs have also submitted a declaration from a peer support and crisis hotline detailing a 111.5% increase in calls from LGBT individuals expressing worry about being able to access health care, including a proportional increase in calls from individuals in plaintiff states California, Massachusetts, and New York. *See Vera Suppl. Decl.* ¶¶ 8-9 (Ex. 55).

⁷ *See also New York v. Sebelius*, No. 07-cv-1003, 2009 WL 1834599, at *12 (N.D.N.Y. June 22, 2009) (“[A] *parens patriae* claim seeking to compel federal compliance with federal law is permissible where a State’s independent quasi-sovereign interest is implicated.”); *Abrams v. Heckler*, 582 F. Supp. 1155, 1159 (S.D.N.Y. 1984) (holding that state may bring a suit under *parens patriae* standing “to enforce a federal statute”); *City of New York v. Heckler*, 578 F. Supp. 1109, 1122-23 (E.D.N.Y. 1984) (holding that state may bring APA claims against a federal agency under *parens patriae* authority to enforce APA and social security statute), *aff’d on other grounds*, 742 F.2d 729 (2d Cir. 1984); *New York v. Schweiker*, 557 F. Supp. 354, 358, 362 (S.D.N.Y. 1983) (holding that state had standing on behalf of “citizens whose health and welfare they are charged with protecting”); *New York v. United States*, 65 F. Supp. 856, 872 (N.D.N.Y. 1946) (same), *aff’d*, 67 S. Ct. 1207 (1947).

will when it comes to federal agencies violating statutes”). Accordingly, the States may invoke their *parens patriae* interests to sue Defendants.

E. *Washington v. HHS* is distinguishable and does not control here.

Defendants insist that the States lack standing to contest the 2020 Rule because a district court in the Western District of Washington found that Washington State lacked standing to secure a preliminary injunction against three of the Rule’s provisions. Defs.’ Mem. 1 (citing *Washington v. HHS*, No. 20-cv-1105 (JLR), 2020 WL 5095467 (W.D. Wash. Aug. 28, 2020)). To the extent that Defendants suggest that the *Washington* court ruled, as a matter of law, that Washington could *never* have established standing, they are wrong. First, with respect to the injury-in-fact requirement, the court found that Washington failed to adduce sufficient evidence to establish injury resulting from the Rule’s rescission of certain LGBTQ protections, but “could overcome this deficiency if it could provide specific evidence establishing that a third-party provider or insurer planned to discriminate against or limit its healthcare coverage for LGBTQ individuals once the 2020 Rule went into effect.” 2020 WL 5095467, at *8. At the pleading stage, however, a plaintiff need not provide specific evidence of a health program’s plans to discriminate to establish standing. Threatened harm need not be “literally certain” to come about. *Ross v. AXA Equitable Life Ins. Co.*, 115 F. Supp. 3d 424, 433 (S.D.N.Y. 2015) (quoting *Clapper*, 568 U.S. at 414 n.5). It is enough to allege a substantial risk that the harm will occur. *Susan B. Anthony List*, 573 U.S. at 158.

Second, the *Washington* court held that the administrative costs were not traceable to the Rule because they were “voluntary, self-inflicted costs that Washington imposes based on its desire to inform Washingtonians of changes in federal law.” 2020 WL 5095467, at *10 (quotation marks omitted). But courts in the Second Circuit have held otherwise. *See supra* Part I.A. Recently, another court in this District flatly rejected this argument at the motion to dismiss

stage, reasoning that “[t]he States have plausibly alleged that they will incur administrative costs by reviewing current guidance . . . and either retracting or issuing new or revised guidance” because “these increased administrative costs are ‘predictable, likely, and imminent.’” *Scalia I*, 464 F. Supp. 3d at 545 (quoting *USCIS*, 408 F. Supp. 3d at 1124). The court affirmed its holding on summary judgment based on declarations similar to those submitted with the States’ summary judgment motion here. *See Scalia II*, 2020 WL 5370871, at *11 (“The States have provided evidentiary support for those allegations, so the Court adheres to its conclusion in *Scalia I*”).

Finally, contrary to the *Washington* court’s characterization of Washington’s injuries, the States’ injuries here do not accrue from a mere “desire” to inform their residents of a change in federal regulatory protections. *Washington*, 2020 WL 5095467, at *10. Rather, as alleged in the Complaint and discussed above, the 2020 Rule requires them to address and counteract new conflicts between federal and state nondiscrimination protections arising from the 2020 Rule; assuage confusion and fear among residents, providers, and other regulated entities that has predictably resulted from the Rule’s rescission of nondiscrimination protections and other changes to HHS’s existing Section 1557 regulations; and to fill the enforcement gap created by the Rule. These harms are sufficient to allege standing at the pleading stage and, with the evidence Plaintiffs have provided with their summary judgment motion, to prove it.

II. Plaintiffs have standing to challenge each of the core provisions of the 2020 Rule.

As explained above, the States have standing to challenge the Rule as a whole for “each claim” they assert under the APA and the Fifth Amendment and “for each form of relief sought,” *i.e.*, vacatur. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). But even if, as Defendants suggest (*see* Defs.’ Mem. 9), Plaintiffs must make a specific showing of standing as to each challenged provision of the 2020 Rule, Plaintiffs have done so.

A. Plaintiffs have standing to challenge the 2020 Rule’s redefinition of “health program or activity” to exclude certain health insurers and HHS programs from the Rule’s scope.

Plaintiffs challenge the 2020 Rule’s redefinition of covered “health program or activity,” 85 Fed. Reg. at 37,244-45 (§ 92.3), which narrows the scope of entities previously covered by the 2016 regulations in three ways. *First*, the 2016 regulations applied to “every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.” 81 Fed. Reg. at 31,466 (former § 92.2). The 2020 Rule rescinded that provision and now defines “health program or activity” to refer only to “all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance” or, “[f]or any entity not principally engaged in the business of providing healthcare, . . . to such entity’s operations only to the extent any such operation receives Federal financial assistance.” 85 Fed. Reg. at 37,244 (§ 92.3(b)). *Second*, the 2016 Rule applied to all operations of health insurers receiving federal assistance; the 2020 Rule now excludes many insurers and health plans by providing that “an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare.” *Id.* at 37,244-45 (§ 92.3(c)). *Third*, under the 2016 Rule, all health programs and activities operated by HHS were subject to Section 1557’s requirements, 81 Fed. Reg. at 31,466 (former § 92.2); now, all HHS programs except for those “established under” Title I of the ACA are excluded from the Rule’s scope, 85 Fed. Reg. at 37,244 (§ 92.3(a)). In short, any person facing discrimination by an insurer or other entity covered by the 2016 Rule, but no longer covered by the 2020 Rule, will have no administrative recourse with HHS and will need to pursue their claims with state agencies.

Plaintiffs allege that these changes were not in accordance with law and are arbitrary and capricious under the APA. *See* Compl. ¶¶ 99-104, 257-65, 272-79. Plaintiffs have standing to challenge these aspects of the 2020 Rule because they will further increase divergence between federal and state laws, will increase confusion among health care providers, insurers, and consumers, and will result in more frequent discriminatory actions by entities that are no longer within the scope of Section 1557’s express regulatory definitions. *See id.* ¶¶ 177, 207, 209-10. Plaintiffs allege that each of these effects will cause them to bear additional costs in the form of: (1) additional regulatory and administrative activities to address differences between federal and state laws, (2) increased enforcement expenses created by the vacuum of HHS’s enforcement of Section 1557 as to entities and forms of discrimination no longer covered under the 2020 Rule, and (3) compounded public health care costs for services to persons who avoid seeking health care due to their expectation that they will face discrimination by entities no longer covered under the 2020 Rule. *See* Compl. ¶¶ 86(b), 99-104, 209-10, 248-50, 259.

Once again, Defendants’ challenge to Plaintiffs’ assertion of standing relies upon the argument that Plaintiffs’ allegations “rest on speculation about the decisions of independent actors.” Defs.’ Mem. 30 (citing *Clapper*, 568 U.S. at 414). Not so. Plaintiffs challenge the 2020 Rule’s new exclusion of many health programs and activities from the regulation’s scope and the concomitant inability of the States’ residents to file discrimination complaints against those entities with HHS. Plaintiffs have plausibly alleged that they will face increased administrative and enforcement costs as a result of these changes. It is unreasonable to assume, as Defendants urge (*see* Defs.’ Mem. 30), that newly-exempted insurers will *never* deny or limit coverage to an

individual on a discriminatory basis.⁸ “Indeed, even HHS admits that the 2016 Rule ‘likely induced many covered entities to conform their policies and operations’ to the regulation’s definition of sex discrimination, and that elimination of that definition may cause some covered entities to ‘revert to the policies and practices they had in place before’ the 2016 Rule.”

Whitman-Walker Clinic, Inc. v. U.S. Dep’t of Health & Human Servs., No. 20-cv-1630, 2020 WL 5232076, at *14 (D.D.C. Sept. 2, 2020) (quoting 2019 NPRM, 84 Fed. Reg. at 27,876).

It is even less reasonable to assume that insured individuals will not seek to file discrimination complaints against insurers for actual or perceived discrimination, even in instances where no violation is ultimately found. If a state enforcement agency in any one of the Plaintiff States receives even one complaint against an insurer that would previously have gone to HHS—which Plaintiffs plausibly allege will result from these changes—Plaintiffs have standing to challenge this provision since Article III requires only an “identifiable trifle” of injury, and for just one plaintiff, to establish standing. *LaFleur*, 300 F.3d at 270; *see Dep’t of Commerce*, 139 S. Ct. at 2565. This Court is not being asked, as *Washington* suggests, to assume “that entities who are no longer subject to Section 1557 will freely engage in discrimination against LGBTQ individuals,” *Washington*, 2020 WL 5095467, at *12. It suffices that *any* of the States’ residents experiencing discrimination by such an entity can no longer file such a complaint with HHS and will need to do so with a state agency, resulting in additional enforcement costs to that State.⁹

⁸ Plaintiffs’ motion for summary judgment includes evidence that insurers operating in at least two Plaintiff States have already instituted discriminatory new exclusions on transition-related care for the 2021 plan year in response to the 2020 Rule. *See* Keith Decl. ¶¶ 10-12 (Ex. 49).

⁹ *See, e.g.,* Kish Suppl. Decl. ¶ 5 (Ex. 54) (describing California DFEH’s receipt of complaint alleging discrimination against transgender individual and need for agency to expend time and resources to investigate),

Regardless of how any individual insurer responds to the 2020 Rule's changes to the definition of covered entity, Plaintiffs have plausibly alleged that they have incurred or are at substantial risk of incurring administrative and enforcement costs as a result of the revised scope of the Rule's application. Moreover, Plaintiffs have plausibly alleged that they are at substantial risk of incurring public health costs and injury to their quasi-sovereign interests in the health and well-being of their residents where discriminatory insurance exclusions, coverage determinations, or denial of services by non-covered entities result in delayed or denied health care. Compl. ¶¶ 222-25, 248-56. Particularly where such discrimination occurs in entities not subject to state discrimination laws—*e.g.*, Federal Employee Health Benefit plans, Medicare Part B plans, and health programs operated by HHS that serve the States' residents—Plaintiffs are likely to experience increased demand on their public health systems and public benefits programs, and increased uncompensated care costs, resulting from delayed or denied health care. *Id.* ¶¶ 251-56. These allegations are sufficient to support Plaintiffs' standing.

For similar reasons, Plaintiffs have standing to challenge the 2020 Rule's exclusion of non-Title I health programs and activities administered by HHS. The 2020 Rule's removal of most federally-administered health care programs from Section 1557's scope will drastically impact the ability of victims of discrimination to obtain relief. This means that any of the States' residents who faces discrimination in a program or activity administered by HHS's Centers for Medicare and Medicaid Services, Indian Health Service, Health Resources and Services Administration, and Substance Abuse and Mental Health Services Administration, among others, will have no administrative recourse. *See* 81 Fed. Reg. at 31,446; *Whitman-Walker*, 2020 WL 5232076, at *5. Such discrimination will, as with other health programs or activities, predictably lead to delayed or denied care or access to health services for the States' residents, further taxing

the States' public health and public benefits programs, and causing increased uncompensated care costs, for the reasons described above. Defendants' suggestion that individuals suffering discrimination under these programs can seek judicial relief through a private lawsuit under the Fourteenth Amendment is speculative at best, and the potential availability of litigated relief does not obviate the significant harms to the States and their residents resulting from delayed or denied access to health care and services.

The injuries alleged by Plaintiffs to be caused by the redefinition of covered entities are plainly redressable through this litigation: a vacatur of Section 92.3 of the 2020 Rule would restore the language from the 2016 Rule providing for a broader application of the Rule to insurers and non-Title I HHS programs. Defendants mistakenly rely on *Diamond*, 476 U.S. at 64, in support of their contentions that the many injuries attributable to the 2020 Rule's redefinition of covered entity are not redressable through this litigation. But *Diamond* held only that a private citizen does not have standing to seek judicial relief compelling government action to prosecute a law absent allegations of direct harm, 476 U.S. at 66-67; it did not discuss redressability. Again, Plaintiffs do not seek a remedy compelling HHS to take any specific enforcement action. Rather, they seek vacatur of a Rule that violates the APA by improperly excluding certain entities from the Rule's scope. Compl. at 92 (Request for Relief).

Thus, Plaintiffs have met the requirements of standing to challenge the 2020 Rule's modification to the definition of entities covered under Section 1557.

B. Plaintiffs have standing to challenge the 2020 Rule's rescission of the definition of "on the basis of sex."

Plaintiffs challenge the 2020 Rule's rescission of the definition of "on the basis of sex," which enumerated the forms of prohibited sex discrimination to "include[], but . . . not [be] limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy,

or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity,” 81 Fed. Reg. at 31,467 (former § 92.4), and the related requirement that covered health programs and activities generally treat transgender people consistent with their gender identity, *id.* at 31,471 (former § 92.206), as arbitrary, capricious, and contrary to law in violation of the APA and as a violation of the Fifth Amendment’s equal protection principles. Compl. ¶¶ 86, 89-95, 257-65, 272-84. Plaintiffs also challenge so-called “conforming amendments” to other HHS regulations to remove prohibitions on gender identity and sexual orientation discrimination to “conform” with HHS’s erroneous view that discrimination “on the basis of sex” does not encompass those forms of discrimination. *Id.* ¶¶ 86, 98.

Plaintiffs have plausibly alleged harms to their proprietary and quasi-sovereign interests traceable to these changes, in addition to the overall efforts to respond to the Rule identified above. *Id.* ¶¶ 175, 177, 183, 184, 188-91, 195-96, 202, 203, 211-21, 223-24, 226-40. The Complaint plausibly alleges that LGBTQ individuals, women, and others seeking reproductive health care have experienced and will continue to experience confusion and fear about what, if any, civil rights protections apply to them in the health care context. *Id.* ¶¶ 222-26, 231-33, 240; *see also* Vera Suppl. Decl. ¶ 8 (Ex. 55) (reporting an 87 percent increase in callers to Trans Lifeline who expressed worry about being able to access mental health care after the 2020 Rule was published). As with the other changes, this reasonable confusion and fear will predictably increase inquiries and complaints to state agencies, impose increased enforcement costs on the States to enforce their own civil rights laws for these communities, and likely result in delayed, denied, or inadequate health care that will impose added public health costs on the States. Compl. ¶¶ 222-26, 231-33, 240.

The States will be harmed by these predictable consequences of the Rule. *Id.* ¶¶ 251-56.

For example, New York, California, Colorado, Connecticut, Oregon, and Wisconsin, among others, have plausibly alleged a need to create or update public outreach materials to educate LGBTQ residents about their rights and mitigate concerns that they may have no redress for discrimination in health settings. *Id.* ¶¶ 184-85, 189, 191, 202, 205. Similarly, New York, California, Massachusetts, Colorado, Connecticut, Illinois, New Jersey, Oregon, Rhode Island, Vermont, and Wisconsin, among others, have plausibly alleged that they will or may incur expenses to notify regulated entities of their obligations and address confusion caused by the rescission of protections for LGBTQ people and women. *Id.* ¶¶ 183, 186-91, 195, 202-05. Several Plaintiff States, including New York, Colorado, Illinois, and Maryland, have adopted or initiated rulemaking on new policies to ensure that their LGBTQ residents continue to have nondiscrimination protections after the Rule’s elimination of the express federal regulatory protections. *Id.* ¶ 183, 189, 198-99.

In addition, Plaintiffs have specifically alleged in their Complaint that the rescission of the definition of “on the basis of sex” and the express requirement that transgender people be treated consistent with their gender identity will predictably increase their enforcement costs based on an anticipated increase of discrimination complaints by transgender and other LGBTQ people, and will have adverse public health effects resulting from delayed or denied care for LGBTQ people and women resulting from discrimination by providers and insurers that those entities no longer believe to be illegal following the 2020 Rule’s changes. *Id.* ¶¶ 211-13, 215-16, 219, 222-40; *see also* Vera Suppl. Decl. ¶¶ 5-6, 8 (Ex. 55).

These injuries all suffice to establish the States’ standing to challenge these provisions and are redressable, at least in part, by the requested vacatur of the Rule. As Defendants concede, “[v]acating the challenged 2020 Rule would thus leave Plaintiffs with the non-vacated

portions of the 2016 Rule.” Defs.’ Mem. 29. Even assuming vacatur of the 2020 Rule would not restore the phrases “gender identity” and “termination of pregnancy” struck from the 2016 Rule by the district court in *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 695 (N.D. Tex. 2016), the restored definition would once again enumerate discrimination based on “pregnancy, false pregnancy, . . . or recovery therefrom, childbirth or related medical conditions, [and] sex stereotyping” as forms of prohibited discrimination on the basis of sex. 81 Fed. Reg. at 31,467 (former § 92.4). When HHS chose to define the phrase “on the basis of sex” in the 2016 Rule, it did so to reflect the current state of nondiscrimination law. 81 Fed. Reg. at 31,387-88. Restoring the non-vacated portions of the definition would be consistent with *Bostock v. Clayton Cty.*, 140 S. Ct. 1731 (2020), and prevailing case law, reducing the States’ harms incurred in responding to confusion by residents and regulated entities caused by the definition’s rescission. Moreover, because courts have interpreted the sex stereotyping protections under Title IX, Title VII, and other laws to protect transgender people from discrimination based on their transgender status, *see, e.g., Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1049-50 (7th Cir. 2017) (Title IX); *Glenn v. Brumby*, 663 F.3d 1312, 1321 (11th Cir. 2011) (Title VII), restoring the definition that includes “sex stereotyping” and pregnancy-related conditions will clarify that these forms of discrimination are protected by Section 1557. The possibility of this partial redress is enough to establish standing. *Whitman-Walker*, 2020 WL 5232076, at *14-15.

Vacatur would also restore the 2016 Rule’s requirement that covered health programs or activities treat transgender people consistent with their gender identity, 81 Fed. Reg. at 31,471 (former § 92.206), which was not vacated by the *Franciscan Alliance* court. Restoring this provision will clarify that transgender people are protected by Section 1557 and reduce the fear

and confusion caused by the rescission of these provisions.¹⁰

Defendants' reliance on *Clapper* is, for the reasons explained above, misplaced. *See supra* Part II.A. Plaintiffs are not asserting standing based on their own "subjective apprehensions," Defs.' Mem. 17, but on the substantial likelihood that they will suffer injuries to their proprietary and quasi-sovereign interests based, in part, on the predictable fear and confusion by their residents, providers, and regulated entities traceable to the Rule. And while Defendants suggest that Plaintiffs can simply avoid added enforcement costs by choosing not to enforce their own laws, Defs.' Mem. 25, that ignores the nondiscretionary nature of many of the States' civil rights investigative obligations, not to mention the States' fundamental interest in protecting the civil rights of all of their residents. *See supra* Part I.B.

Plaintiffs therefore have standing to challenge the 2020 Rule's rescission of the enumerated definition of "on the basis of sex" and the related requirement that transgender people be treated consistent with their gender identity.

C. Plaintiffs have standing to challenge the 2020 Rule's rescission of prohibitions against insurance discrimination against transgender people.

Plaintiffs also challenge the 2020 Rule's removal of the 2016 Rule's provisions prohibiting health insurers from discriminating against transgender people. 81 Fed. Reg. at 31,471-72 (former § 92.207(b)(3)). The 2016 Rule prohibited insurers from:

(3) [d]eny[ing] or limit[ing] coverage, deny[ing] or limit[ing] coverage of a claim, or impos[ing] additional cost sharing or other limitations or restrictions on coverage, for any health services that are ordinarily or exclusively available to

¹⁰ Defendants' contention that "Plaintiffs would like this Court to direct HHS to promulgate a rule that explicitly defines discrimination 'on the basis of sex' to include sexual orientation discrimination," Defs.' Mem. 30, misreads Plaintiffs' complaint and mischaracterizes their requested relief: vacatur of the Rule. To the extent HHS wishes to further amend its Section 1557 regulations to add sexual orientation discrimination to the definition of discrimination "on the basis of sex" in light of the Supreme Court's decision in *Bostock*, it may certainly do so, but Plaintiffs are not requesting that the Court order such relief.

individuals of one sex, to a transgender individual based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available;

(4) Hav[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition; or

(5) Otherwise deny[ing] or limit[ing] coverage, deny[ing] or limit[ing] coverage of a claim, or impos[ing] additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual.

81 Fed. Reg. at 31,471-72 (former § 92.207(b)(3)-(5)).

Plaintiffs challenge the elimination of these requirements as arbitrary, capricious, and contrary to law, in violation of the APA, and as a violation of the equal protection guarantee of the Fifth Amendment. The bases for Plaintiffs' standing to challenge the rescission of these provisions is virtually identical to those providing standing to challenge the elimination of other protections for transgender people in the Rule and the Rule's exclusion of many insurance companies from the Rule's scope. *See supra* Parts I.A., I.B. Like the rescission of the definition of "on the basis of sex" and requirement that transgender people be treated consistent with their gender identity, the removal of these protections will generate further confusion and fear in the transgender community about their ability to obtain medically necessary transition-related care and insurance coverage to pay for those treatments. The States will need to address that fear and confusion, and the related public health consequences of delayed or denied care, including for untreated or inadequately treated gender dysphoria. Compl. ¶¶ 222-56.

In addition, Plaintiffs' Complaint alleges that the removal of these prohibitions will harm their proprietary and quasi-sovereign interests. *Id.* ¶¶ 183, 195, 198, 213, 224. For example, in response to the 2020 Rule, New York's Department of Financial Services amended the State's insurance regulations to expressly prohibit policy exclusions for treatments related to gender

dysphoria, and updated its guide for transgender New Yorkers about their rights to obtain health insurance coverage for gender-affirming care. *Id.* ¶ 183. Illinois issued bulletins to insurers and providers to remind them of their obligations not to discriminate against LGBTQ people, and has proposed a rulemaking to expand existing protections to more health insurers and plans. *Id.* ¶¶ 195-96. Other States have needed to clarify the scope of their gender identity protections for residents, providers, and insurers. *Id.* ¶¶ 187-92, 200-06.

Defendants bizarrely and inaccurately characterize the 2016 Rule’s prohibitions on insurance coverage exclusions and discriminatory coverage determinations as prohibiting “the flexible treatment of gender dysphoria.” Defs.’ Mem. 45. In truth, the elimination of those provisions allows insurers to deny *all* treatments for gender dysphoria, regardless of medical necessity. The 2016 Rule’s prohibitions simply required insurers to provide comparable coverage for like services, regardless of whether they were to treat gender transition or another condition, 81 Fed. Reg. at 31,471-72 (former § 92.207(3), (5)), and to bar insurers from maintaining categorical exclusions for transition-related care that would deny coverage to transgender people for medically necessary care, *id.* at 37,472 (former § 92.207(4)). Nothing in those provisions applied to providers at all, let alone limited their “flexibility” in providing medically necessary care to their patients, and the 2016 Rule expressly permitted insurers to deny coverage for services that are not medically necessary or make other coverage determinations for transition-related care for non-discriminatory reasons. *Id.* at 31,472 (§§ 92.207(b)(5), (d)).

Vacatur of the 2020 Rule and the restoration of the 2016 Rule’s prohibitions on insurance discrimination against transgender people will redress Plaintiffs’ injuries on this front.

D. Plaintiffs have standing to challenge the 2020 Rule’s adoption of religious exemptions from Title IX.

Plaintiffs challenge the 2020 Rule’s incorporation of Title IX’s broad religious exemption and abortion neutrality provisions as contrary to law, and in excess of HHS’s statutory authority, in violation of the APA. Compl. ¶¶ 115-21, 257-79.

Plaintiffs have standing to challenge the incorporation of Title IX’s exemptions for substantially similar reasons to those providing standing to challenge the other revisions. The Complaint alleges that the States have been or will be required to expend additional resources in response to these new exemptions to: (1) clarify to covered entities and members of the public that existing State laws still cover religiously affiliated providers who now have broad exemptions under the 2020 Rule, (2) investigate additional claims of discrimination against religiously affiliated providers who have engaged in conduct now permitted under the newly available religious exemptions created by the 2020 Rule, and (3) provide additional health care services to persons who avoid seeking health care due to their expectation that they will face discrimination by providers due to the 2020 Rule’s religious exemption. *See id.* ¶¶ 120-21, 177-80, 182-205, 207-25, 233-40. The Complaint alleges that because “religiously affiliated health systems and insurers are becomingly increasingly common in the American health care system and, for many people, are the only options available,” the incorporation of these exemptions “will, in many cases, effectively deny access to medically necessary care because of discrimination,” *id.* ¶ 121, particularly where religious entities invoke those exemptions to deny or limit reproductive health care or LGBTQ health services.

Defendants first counter Plaintiffs’ standing to challenge these provisions by positing that “confusion” among covered entities and protected classes regarding the obligations of religiously affiliated health care providers to comply with the law does not give rise to an injury to support

standing. *See* Defs.’ Mem. 26-27. But the cases Defendants rely on are inapposite, because they involve a plaintiff who alleged injuries based on their own confusion regarding whether and how a federal regulation may apply. *See Gerber Prods. Co. v. Perdue*, 254 F. Supp. 3d 74, 81 (D.D.C. 2017) (describing alleged injuries as “great uncertainty and an un-level playing field” regarding the plaintiff’s interactions with the federal government’s regulatory programs following promulgation of challenged regulatory actions); *City & Cty. of San Francisco v. Whitaker*, 357 F. Supp. 3d 931, 944 (N.D. Cal. 2018) (plaintiffs lacked standing based on uncertainty as to federal requirements following agency’s rescission of sub-regulatory guidance documents); *New England Power Generators Ass’n, Inc. v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013) (rejecting plaintiff’s theory of standing alleging that federal regulatory action would lead to “uncertainties regarding rate stability” in the broad energy marketplace where causation rested on “the potential for FERC to issue future, contrary orders.”). Here, by contrast, Plaintiffs allege that they are injured through reasonably-incurred administrative and regulatory costs they must undertake to inform regulated entities and the public that state law protections remain in force for all health care providers—including religiously affiliated health care providers—despite newly expanded federal regulatory exemptions for these entities. Compl. ¶¶ 177-82; *see also* Kish Suppl. Decl. ¶¶ 5, 7 (Ex. 54) (describing California’s recent administrative and enforcement expenditures). It is well-established that these allegations support standing. *See, e.g., Scalia I*, 464 F. Supp. 3d at 545; *see also Dep’t of Labor*, 363 F. Supp. 3d at 126.

Contrary to Defendants’ arguments, Plaintiffs’ injuries from the 2020 Rule will not be avoided simply because they have anti-discrimination statutes and regulations that do not include religious or abortion exemptions. *See* Defs.’ Mem. 28. Plaintiffs will incur additional costs resolving the confusion created from this divergence in state and federal requirements and

investigating and remediating additional allegations of discrimination by entities subject to federal regulatory exemptions that would have otherwise been accepted and investigated by OCR. Compl. ¶¶ 207-21.

Nor can Defendants credibly dispute that the 2020 Rule will cause the alleged injuries supporting Plaintiffs’ standing. Defendants fail to distinguish *Massachusetts v. HHS*, 923 F.3d 209, 223-26 (1st Cir. 2019), in which the First Circuit held that Massachusetts had standing to challenge the federal government’s promulgation of regulations that would permit employers with religious or moral objections to contraception to obtain exemptions from providing health insurance coverage to employees and their dependents for FDA-approved contraceptive care. The Court held that “a plaintiff need not demonstrate that it is literally certain that the harms they identify will come about” and that “a relatively small economic loss—even an identifiable trifle—is enough to confer standing.” *Id.* at 222, 225 (internal quotations omitted). The Commonwealth presented evidence of imminent fiscal injury because there was “a substantial risk that the rules will cause women in the Commonwealth to lose their contraceptive coverage,” that some women who lose coverage “will then obtain state-funded contraceptive services or prenatal and postnatal care for unintended pregnancies,” resulting in increased costs to the Commonwealth’s public health programs. *Id.* at 223.

As in *Massachusetts*, the federal government here primarily contests Plaintiffs’ ability to demonstrate that any specific provider will utilize the new exemptions. *See* Defs.’ Mem. 27-28. But Plaintiffs’ standing to challenge the religious and abortion exemptions does not hinge on “the possibility of third-party, religiously affiliated providers *actually* discriminating against LGBTQ patients, but rather on patients’ genuine *fear* of encountering discrimination when seeking care from such institutions.” *See Whitman-Walker* 2020 WL 5232076, at *15. “Anxiety

surrounding the possibility of discrimination and denial of treatment is substantially likely to provoke” individuals to turn to health care programs that do not engage in discriminatory behavior, such as Plaintiffs’ public health and public benefits programs, or to avoid seeking care at all. *See id.* at *12.

Regardless, the Complaint plausibly alleges that there is a “substantial risk” that health care consumers will perceive that the 2020 Rule’s religious and abortion exemptions will increase the likelihood that they will be denied care for discriminatory reasons, thereby leading to increased expenditures within Plaintiffs’ public health care programs. *See* Compl. ¶ 121. HHS previously reasoned in promulgating the 2016 Rule that “a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results,” and that such an exemption would especially harm people who may “have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions.” 81 Fed. Reg. at 31,380. Indeed, Defendants’ claimed impetus for adopting the 2020 Rule’s adoption of the religious exemption and abortion provisions was to respond to some religiously affiliated providers’ challenge to the 2016 Rule. *See* Defs.’ Mem. 7 (citing 85 Fed. Reg. at 37,205). It is therefore reasonable to expect that there is a “substantial risk” that religiously affiliated providers will use the new exemptions to limit or deny care,¹¹ and

¹¹ The 2020 Rule’s administrative record is replete with comments observing the likelihood that religiously affiliated providers will use the new exemptions to deny care. *See, e.g.*, AR-00154252-253 (Nat’l Asian Pac. Women’s Forum cmt.); AR-00141595-596 (NARAL Pro-Choice Am. cmt.); AR-00153954-957 (Nat’l Hispanic Leadership Agenda cmt.); AR-00144889-890 (Nat’l All. of State & Territorial AIDS Dirs. cmt.); AR-00142062-068 (law and religion scholars cmt.); AR-00129685-687 (Am. Med. Student Ass’n cmt.); AR-00117576-577 (Ass’n of Am. Med. Colls. cmt.); AR-00143086-087 (Am. Acad. of Pediatrics & Soc’y for Adolescent Health & Med. cmt.); AR-00162009-011 (Gender Justice cmt.); AR-00152654-655 (HIV Health

to expect that consumers will anticipate this and engage in avoidance behaviors. *Cf. New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 576 (S.D.N.Y. 2019), *aff'd*, 139 S. Ct. 2551 (2019) (holding that where “statistical analysis, common sense, or record evidence” may support an inference that third parties will react to a challenged government action in a predictable way, then the causation requirement is met).

Vacatur of the 2020 Rule, which will restore provisions of the 2016 Rule, will fully redress Plaintiffs’ injuries caused by the newly created religious and abortion regulatory exemptions. *See Whitman-Walker*, 2020 WL 5232076, at *15 (“Just as explicitly incorporating Title IX’s religious exemption into Section 1557 spurred LGBTQ patients’ fear of discrimination, enjoining such incorporation would likely palliate such fear . . .”).

Thus, Plaintiffs have standing to challenge the 2020 Rule’s improper incorporation of Title IX’s religious exemptions and abortion neutrality requirements.

E. Plaintiffs have standing to challenge the 2020 Rule’s modifications to prohibitions on discrimination against LEP individuals.

Plaintiffs challenge the 2020 Rule’s substantial amendments to provisions requiring covered health programs and activities to provide meaningful access to their programs to LEP individuals. Compl. ¶¶ 105-14. This includes the Rule’s replacement of the 2016 Rule’s requirement that each “covered entity shall take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered

Care Access Working Grp. cmt.); AR-00154064-067 (Nat’l Latina Inst. for Reprod. Health); AR-00164147-149 (Planned Parenthood cmt.); AR-00152883-884, AR-00152890-891 & n.3 (Ctr. for Am. Progress cmt.); AR-00137611-614 (Human Rights Watch cmt.); AR-00164146-147 (Planned Parenthood cmt.); AR-00154066-067 (Nat’l Inst. for Latina Reprod. Health cmt.); AR-00164244-245 & n.91 (Lambda Legal cmt.); AR-00159741-742 (Nat’l Inst. for Reprod. Health cmt.); AR-00151790 (Maine Family Planning cmt.); AR-00109103 & n.13 (Am. Psychiatric Ass’n cmt.).

in its health programs and activities” and related requirements, 81 Fed. Reg. at 31,470 (former § 92.201), with a watered-down standard merely requiring that entities “take reasonable steps to ensure meaningful access” to LEP people in general, and authorizing entities to provide no language assistance services at all if, following a self-assessment, the entity determines that it is not obligated to do so. 85 Fed. Reg. at 27,245 (§ 92.101(a)-(b)). Plaintiffs also challenge the Rule’s rescission of the 2016 Rule’s requirement that covered entities notify LEP individuals of their rights and ability to request language assistance services through translated notices and taglines, Compl. ¶¶ 112-14, although Defendants do not challenge Plaintiffs’ standing to challenge those provisions.

Plaintiffs allege that these changes were not in accordance with law and are arbitrary and capricious under the APA and will likely result in many covered entities denying meaningful language assistance services to many LEP individuals. *See id.* ¶¶ 105-40, 257-65, 272-79. Plaintiffs have standing to challenge these aspects of the 2020 Rule because they will be injured due to the additional administrative and regulatory costs required to address the new divergence between state and federal laws, and to expend public health resources to address the increased health disparities faced by LEP individuals. *See id.* ¶¶ 175, 177, 181-82, 190, 211, 241-47.

Increased barriers to care for LEP individuals as a result of the 2020 Rule, and the attendant costs to the States in the form of administrative, enforcement, and public health costs, are reasonably predictable. When promulgating the 2016 Rule, HHS credited evidence that LEP individuals face discrimination and other barriers to health care, with negative downstream consequences on individual health, community health care, and the distribution of health care resources. *See* 81 Fed. Reg. at 31,431, 31,459. As HHS found then:

safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options,

the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other myriad purposes. This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.

Id. at 31,431. HHS relied on studies documenting the barriers to care for LEP individuals and the benefits to patients and health care providers of having robust language assistance services—including relevant studies that HHS itself had published. *Id.* at 31,413 n.173, 31,459, 31,416 n.192, 31,459. HHS also determined that “reliable language assistance services” were necessary to combat this problem and thus implement Section 1557’s prohibition against national origin discrimination. *Id.* at 31,431. In line with HHS’s prior findings, commenters cautioned that such “increased discrimination in healthcare . . . would [in turn] lead people to delay or forego healthcare and would result in adverse health outcomes and greater overall healthcare costs to individuals,” *id.* at 37,165, and that a “lack of understanding in a medical setting could cause harm and possibly death to patients with LEP,” *id.* at 37,210. To ensure that LEP individuals were made aware of their rights and could access health care with adequate language assistance services, HHS promulgated the robust notice, tagline, and language assistance requirements of the 2016 Rule. *Id.* at 31,398; *see* 80 Fed. Reg. 54,172, 54,178 (Sept. 8, 2015) (“Apprising individuals of the availability of communication assistance under Section 1557 will promote both compliance with the law and better health outcomes.”).¹²

Plaintiffs have plausibly alleged that they and their residents have been or will be injured because they must respond to the 2020 Rule’s elimination of these requirements, *see* Compl.

¶¶ 177, 181, 185, 187, 201, 241-47. To ensure LEP residents are informed of their rights under

¹² Numerous commenters warned that the 2020 Rule would likely “result in a number of LEP individuals [being] unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals.” 85 Fed. Reg. at 37,210; *see also id.* at 37,165, 37,175, 37,204, 37,210-12.

both federal and state law in the absence of the former notice requirements, Plaintiffs will expend resources to conduct public education initiatives. *Id.* ¶ 181. The Complaint alleges, for example, that DFEH anticipates conducting a multi-lingual campaign to inform LEP Californians of their rights. *Id.* ¶ 185.¹³ Massachusetts, New Jersey, and other Plaintiffs will need to inform regulated entities of their continuing obligations to provide language assistance services. *Id.* ¶¶ 177, 187, 201. And the States reasonably expect, as with the other amendments to the Section 1557 regulations, to incur public health costs resulting from delayed, denied, or inadequate health care for LEP individuals unable to access language assistance services because of the Rule’s weakened protections. *Id.* ¶ 245. Challenges related to the COVID-19 pandemic will compound these problems. *Id.* ¶¶ 246-47.

These injuries are all redressable through a vacatur of the 2020 Rule. Specifically, an order vacating the 2020 Rule will return the status quo of the 2016 Rule, which included robust requirements to provide each LEP individual “meaningful access” and to provide notices and taglines with each significant communication. Such an order will obviate the need for States to expend the resources they already have or will have to incur to respond to the 2020 Rule.

Thus, Plaintiffs have standing to challenge the 2020 Rule’s reduction of protections for LEP individuals.

III. Plaintiffs’ claims are ripe.

Defendants finally assert that the 2020 Rule’s elimination of the definition of “on the basis of sex” and other provisions of the 2020 Rule are not ripe for review. Defs.’ Mem. 36-44.

¹³ Since the Complaint was filed, DFEH has retained a communications firm to develop a statewide, multi-lingual anti-discrimination campaign that will launch in 2021, and has also spent significant time and resources to develop, translate, and disseminate a fact sheet entitled “California Protects the Civil Rights of Immigrants,” which was published on October 26, 2020 in twelve languages. *See* Kish Suppl. Decl. ¶ 7 (Ex. 54).

“Ripeness” entails two separate but “overlapping threshold criteria for the exercise of a federal court’s jurisdiction”—constitutional and prudential ripeness. *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 725 F.3d 65, 109-10 (2d Cir. 2013) (quotation and citation omitted). Both criteria “are concerned with whether a case has been brought prematurely.” *Id.* at 110. The constitutional ripeness inquiry essentially mirrors the Article III standing analysis. *Id.* at 109; *see also Ross*, 524 F.3d at 226. The two-part prudential ripeness inquiry requires that the Court ask “whether the claim is (1) fit for judicial resolution and (2) whether and to what extent the parties will endure hardship if decision is withheld.” *MTBE*, 725 F.3d at 110. Where the issue is purely legal and not in need of “further factual development,” it is fit for judicial resolution. *Susan B. Anthony List*, 573 U.S. at 167.

The challenged provisions of the 2020 Rule are fit for review, and Plaintiffs will suffer hardship in the form of the significant, ongoing injuries described above if the Court does not consider their claims now.

A. The 2020 Rule is a final agency action fit for review under the APA.

Defendants contend that because HHS has not yet applied the Rule to an instance of sex discrimination, Plaintiffs have no evidence that HHS would apply the 2020 Rule in “a manner that will harm Plaintiffs.” Defs.’ Mem. 38. Defendants repeatedly characterize Plaintiffs’ alleged harms as “hypothetical” and nothing more than “abstract confusion” or “mere uncertainty,” and contend that Plaintiffs’ claims will not be ripe until HHS enforces the Rule. Defs.’ Mem. 42-44. But simply calling Plaintiffs’ injuries “hypothetical” does not make them so. As explained above, Plaintiffs’ claims are not contingent on speculative scenarios or HHS’s individual enforcement decisions: They are based on the reasonably predictable harms that have accrued or will accrue because of the 2020 Rule. Compl. ¶¶ 173-256. Plaintiffs challenge a final agency rule, not a future enforcement action. As explained above, LGBTQ individuals, women,

and LEP individuals will reasonably understand HHS's reversal of policy and abandonment of prior protections to strip them of legal protections, increase the likelihood of discrimination by health providers and insurers, and deny them the ability to seek administrative relief from HHS. It predictably falls on Plaintiffs' enforcement agencies and public health care systems to respond to their residents' fears and loss of federal protections.

Indeed, it is well-established that challenges to agency action as arbitrary and capricious are fit for review because the agency's action "necessarily stands or falls on [the] administrative record" and the agency's statutory authority. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1282 (D.C. Cir. 2005). To accept Defendants' argument against ripeness would mean that any decision to eliminate regulatory protections and not replace them would be insulated from judicial review. That is not the law. *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 34 (1983).

Plaintiffs allege that HHS's many reversals of existing policy—including the rescission of the definition of "on the basis of sex" and other protections—are arbitrary and capricious because, whatever HHS's policy rationale, it failed to comply with the APA in making those changes. The Rule did not, as HHS contends, simply "decline" to define "on the basis of sex," Defs.' Mem. 36. Were HHS promulgating Section 1557 regulations for the first time, not defining the phrase "on the basis of sex" may have been justifiable. But HHS was *not* writing on a blank slate; thus, it was required to provide a reasoned explanation as to *why* it rescinded the previous definition. It failed to do so. *Whitman-Walker*, 2020 WL 5232076, at *26; *Walker v. Azar*, No. 20-CV-2834, 2020 WL 4749859, at *10 (E.D.N.Y. Aug. 17, 2020). Regardless, the significance of the rescission of these protections goes to the merits, not to ripeness. The

question of whether Defendants complied with the APA is fit for review.¹⁴

HHS’s sole and repeated justification for its rescission of the definition “on the basis of sex” is the agency’s erroneous view that the 2016 Rule defined the term too expansively. Compl. ¶ 86. This case is therefore nothing like *Aulenback*, where plaintiffs challenged a training manual, but the agency had “not had an opportunity to explain, in an authoritative way, the purpose of the Manual and how it is used.” *Aulenback, Inc. v. Fed. Highway Admin.*, 103 F.3d 156, 167 (D.C. Cir. 1997). Here, the preamble clearly explains HHS’s interpretation of Section 1557, and there is an administrative record on which to assess whether HHS complied with the APA and whether the 2020 Rule is lawful. The 85-page preamble is evidence of the agency’s intent and provides a basis for this Court to determine whether the agency properly explained its wide-ranging amendments to its Section 1557 regulations; Defendants cannot pretend that it is meaningless. *Cf. Walker*, 2020 WL 4749859, at *8.

Despite their claims that the “plain meaning” of the statute controls and that they will follow all applicable court rulings, Defs.’ Mem. 39, Defendants have still not taken a consistent position on whether *Bostock* controls the definition of “on the basis of sex” in the 2020 Rule. Defendants acknowledge but do not concede that Plaintiffs could be correct “that *Bostock* means that Title IX and Section 1557 must incorporate protection for gender identity and sexual orientation discrimination,” meaning that the 2020 Rule would extend protection to LGBTQ individuals on those grounds, *id.* at 23, and state that more concrete cases or “further administrative action[s]” are needed to decide if sexual orientation and gender identity discrimination are included in Title IX’s definition of “on the basis of sex,” *id.* at 39, 41. But

¹⁴ To the extent Defendants also argue that the 2020 Rule’s rescission of other provisions is not ripe for review, Defs.’ Mem. 43, the same analysis applies: a reversal of policy must comply with the APA, and the question of whether HHS did so is reviewable now.

they cannot have it both ways. *Bostock* was decided before the 2020 Rule was published, and yet the Rule makes no mention of it. If HHS believed *Bostock* could control and LGBTQ claims would need to be adjudicated on a case-by-case basis, the agency could have stated as much in the preamble or chosen to delay the Rule's effective date to properly consider *Bostock*'s impact on the Rule. HHS did neither. Finally, although Defendants suggest that courts have not definitively ruled on the application of Title IX and Section 1557 to LGBTQ people, both the Rule and Defendants fail to recognize that courts have consistently held that Title IX and Section 1557 prohibit discrimination against LGBTQ people in opinions issued both before and after *Bostock*.¹⁵

In short, HHS was not serious about engaging with the Supreme Court's ruling in *Bostock*. The agency cannot now contend that Plaintiffs' claims are unripe simply because the agency has claimed in litigation that it has not decided how to apply *Bostock*. It is not that "Plaintiffs would prefer guidance now." Defs.' Mem. 41. By rescinding the definition of "on the basis of sex," repeatedly stating HHS's position that "on the basis of sex" does not include discrimination against transgender people, and refusing to take a position on whether *Bostock* applies to Section 1557, HHS repeatedly emphasized that it does not consider sexual orientation or gender identity discrimination unlawful under Section 1557. Compl. ¶¶ 94, 95, 145-47, 167-72; 85 Fed. Reg. at 37,161-63, 37,166, 37,168, 37,177-80, 37,183-95. Plaintiffs have plausibly alleged that this subjects their LGBTQ residents to fear and uncertainty about their rights,

¹⁵ See *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 593, 619 (4th Cir. 2020) (Title IX); *Adams v. Sch. Bd. of St. Johns Cty.*, 968 F.3d 1286, 1304-05 (11th Cir. 2020) (same); *Whitaker*, 858 F.3d at 1049-50 (same); *Flack v. Wis. Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1014-15 (W.D. Wis. 2019) (Section 1557); *Boyden v. Conlin*, 341 F. Supp. 3d 979, 997, 1002-03 (W.D. Wis. 2018) (same); *Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 953 (D. Minn. 2018) (same); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090, 1098-1100 (S.D. Cal. 2017) (same).

impelling them to seek relief from the States’ enforcement agencies, or delaying necessary health care out of fear of discrimination with resulting public health consequences. Compl. ¶¶ 222-56.

B. Plaintiffs will suffer hardship if judicial review of their claims is delayed.

Plaintiffs’ Complaint and this brief describe the actual, concrete harms that the States are suffering and will continue to suffer that are traceable to the 2020 Rule and redressable by a vacatur of that Rule. Again, Defendants try to minimize Plaintiffs’ injuries as “mere uncertainty” or “fear,” claiming that those are insufficient to establish ripeness. Defs.’ Mem. 42. But as explained above, the States have suffered and will continue to face harms to their proprietary and quasi-sovereign interests—including increased administrative, enforcement, and public health costs traceable to the 2020 Rule. Accordingly, the States will suffer hardship if the Court were to accept Defendants’ invitation to defer a ruling on Plaintiffs’ claims until some later date. This is sufficient to meet the ripeness inquiry’s hardship requirement because they will have an “immediate and substantial impact” on the States. *See Gardner v. Toilet Goods Ass’n*, 387 U.S. 167, 171-72 (1967).

In both cases cited by Defendants, plaintiffs had not suffered any injury. *See Ohio Forestry Ass’n, Inc. v. Sierra Club*, 523 U.S. 726, 732-33 (1998) (plaintiffs challenging agency position that would not actually have an impact on any regulated entity until implemented through subsequent agency permitting actions); *Nat’l Park Hosp. Ass’n v. U.S. Dep’t of Interior*, 538 U.S. 803, 808 (2003) (plaintiffs challenged a position that agency stated it would take in the future if certain contingent events occurred, but which had not yet actually occurred). Here, in contrast, Plaintiffs have alleged actual and imminent injury resulting from the Rule itself—not from HHS’s future enforcement of it. Because Plaintiffs meet the fitness and hardship requirements, their claims are ripe.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendants' motion to dismiss.

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Respectfully submitted,

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